SECTION 1.0: 510(k) SUMMARY

1.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical
340 Lake Hazeltine Drive
Chaska, MN 55318-1029 USA
FDA REGISTRATION NUMBER: 2126666

Contact Person: Tracy Meyer
Title: Regulatory Specialist
Telephone: 952-641-8510
Fax: 952-448-3441

1.2 TRADE NAME (PROPRIETATY NAME)

Hydrophilic Coated Guidewires

1.3 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as guides, guidewires, or spring guidewires. The current classification names and product codes are Wire, Guide, Catheter (DQX).

1.4 CLASS OF DEVICE

The classification names listed above were originally classified as Class II devices by the Cardiovascular (74DQX) Review Panel.

1.5 IDENTIFICATION OF PREDICATE DEVICE(s)

510(k) NUMBER	MANUFACTURER	DEVICE NAME
K000011	Lake Region Medical	Hydrophilic Coated Guidewire

1.6 PROPOSED DEVICE DESCRIPTION

Utilizing proprietary processes, these guides are constructed from a steerable, metallic core (Nitinol) with a radiopaque polymer (polyurethane) jacket and a hydrophilic coating is applied over the jacket. Guidewires are available up to 260cm length and in diameters from 0.018" to 0.038" depending on specific design requirements. Guidewires may have a straight or angled distal tip.

OUTSIDE DIAMETER: 0.018" - 0.038"
LENGTHS: 80cm - 260cm
TIP SHAPE: Straight or Angled

1.7 COMPLIANCE WITH APPLICABLE STANDARDS

The **proposed Hydrophilic Coated Guidewires** is in compliance with ISO 10993, ISO 11070, ISO 15223, EN 980, ISO 594.

Lake Region Medical

PRODUCT: Hydrophilic Coated Guidewires
SUBMISSION DATE: September 30, 2013
SUBMISSION TYPE: Traditional 510(k)

SECTION 1.0: 510(k) SUMMARY

1.8 INTENDED USE STATEMENT

To facilitate the placement of devices during diagnostic and interventional procedures.

1.9 CONTRAINDICATIONS

None Known

1.10 COMPARISON

The proposed Hydrophilic Coated Guidewire is substantially equivalent to the predicate Hydrophilic Coated Guidewire with 510(k) number K000011.

1.11 QUALIFICATION TESTING

The conclusions drawn from non-clinical and biocompatibility testing demonstrate the device is substantially equivalent to the claimed predicate device.

BENCH TESTING

In order to demonstrate equivalence of the proposed hydrophilic guidewire, Lake Region Medical performed testing to establish requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. Test methods were developed using *FDA Coronary and Cerebrovascular Guidewire Guidance* and *ISO 11070:1998*. The following table lists the applicable bench tests performed at baseline and aging:

- Dimensional
- FDA Device Compatibility
- FDA Tensile Strength
- FDA Tip Flexibility
- FDA Coating Adherence/Integrity
- FDA Catheter Compatibility
- FDA Torque Control
- FDA Combined Load
- Packaging Study
- Particulate
- Kink Resistance
- Linear Stiffness
- Lateral Stiffness
- ISO Visual
- ISO Fracture
- ISO Flex
- ISO Corrosion
- ISO Strength of Union
- ISO Radiopacity
- Body Stiffness
- Tip Integrity
- Jacket Durability
- Tip Puncture Resistance
- Coating Performance Testing
- 3 Point Bend

1.11 QUALIFICATION TESTING Continued

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the proposed Hydrophilic Guidewires and has been found to be acceptable:

- ISO Cytotoxicity
- ISO Klingman Maximization Test
- ISO Irritation / Intracutaneous Reactivity
- ISO Systemic Toxicity
- ISO Rabbit Pyrogen
- ASTM Hemolysis
- ISO Complement Activation Assay
- ISO Thrombogenicity
- ISO Lee and White Coagulation
- ISO Prothrombin Time Assay
- ISO Unactivated Partial Thromboplastin Time Assay

1.12 SUBSTANTIAL EQUIVALENCE DATA

The proposed Hydrophilic Coated Guidewire has the same intended use as predicate Hydrophilic Coated Guidewires legally marketed by Lake Region Medical and cleared by 510(k) K000011.

The proposed Hydrophilic Coated Guidewires have the same physical characteristics as the predicate device with the exception of the change to the hydrophilic coating. All required tests results support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 7, 2014

Lake Region Medical
% Tracy Meyer, Regulatory Specialist
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K133155
Trade/Device Name: Hydrophilic Coated Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Guidewire Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: March 5, 2014
Received: March 6, 2014

Dear Tracy Meyer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman
-S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K133155

DEVICE NAME: Hydrophilic Coated Guidewire

INDICATIONS FOR USE:

To facilitate the placement of devices during diagnostic and interventional procedures.

PRESCRIPTION USE *(Part 21 CFR 801 Subpart D)*	X	*AND/OR*	**OVER-THE-COUNTER USE** *(21 CFR 807 Subpart C)*	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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